MAY 1 7 2000

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510(k) Summary

Name and Address of Device Manufacturer Submitting 510(k) Notification:

3M
Medical-Surgical Division
3M Center
St. Paul, MN 55144

Regulatory Correspondent of Device Manufacturer:

Linda Johnsen
Regulatory Affairs Specialist
3M Medical-Surgical Division
Building 275-SW-06
Telephone: 651 737-4376

Date Summary was Prepared: May 11, 2000

Name of Device:

3M Red Dot™ Radiolucent Monitoring Electrode with Conductive Adhesive

Catalog Numbers 2660 & 2670

Classification:

Electrocardiograph electrodes, class II, 21 CFR 870.2360

Intended Use:

The 3M Red Dot™ Radiolucent Monitoring Electrode with Conductive Adhesive are intended for ECG monitoring.

Description:

Each electrode has a backing which includes a laminated conductive adhesive and silver/silver chloride sensing element. They are non sterile, intended for single use. They are radiolucent and have a snap style connection. The electrode components and packaging are latex free. They come packaged in either 3 or 5 electrodes on a strip liner. Each electrode is coated with a different conductive adhesive, the 2670 has a more aggressive adhesive to skin and the 2660 has a mild adhesive to skin.

Indications for Use:

The 2660 & 2670 3M Red Dot™ Monitoring Electrodes can be used in all ECG monitoring applications where standard ECG monitoring electrodes are used. The 2600 series monitoring electrodes may be safely worn up to 3 days. The 2670 electrode has an adhesive that is more aggressive than the 2660 and should be used if the level of adhesion of the 2660 is too low for a particular patient or clinical application.

These electrodes are designed for single use.

Predicate Device:

The predicate devices used for the purpose of substantial equivalence under this submission were the 3M Red Dot™ Monitoring Electrode, catalog number 2259 (preamendment) and 3M Red Dot™ Radiolucent Monitoring Electrode, catalog number 2570 (k970796). The predicate devices under this submission have similar features and have the same intended use (long term ECG monitoring). However the predicate devices have a gel column and a border adhesive. Whereas, the 2260 & 2670 have a conductive adhesive which permits the elimination of the gel column and border adhesive. All of the electrodes have a Ag/Ag Cl sensing element. The 2259 is not radiolucent and the 2570 is radiolucent. They all meet AAMI, have a self life of two years, and are designed for single use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2000

Minnesota Mining and Manufacturing, Co.
C/O Ms. Linda Johnsen
3M Medical-Surgical Division
3M Center, Building 275-5W-06
St. Paul, MN 55144-1000

Re: K000690
3M Red Dot™ Radiolucent Monitoring Electrode with Conductive Adhesive
Regulatory Class: II (two)
Product Code: DRX
Dated: February 28, 2000
Received: February 29, 2000

Dear Ms. Johnsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

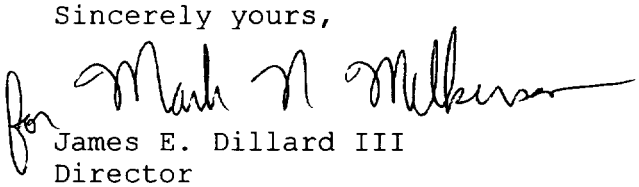
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your

premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address :http.//www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological
Health

Enclosure

510(k) Number (If Known): K000690

Device Name: 3M Red Dot™ Radiolucent Monitoring Electrode with Conductive Adhesive

Catalog Numbers: 2660 & 2670

Indications For Use:

The 2660 & 2670 3M Red Dot™Radiolucent Monitoring Electrode can be used in all ECG monitoring applications where standard ECG monitoring electrodes are used. The 2660 series monitoring electrodes may be safely worn up to 3 days. The 2670 electrode has an adhesive that is more aggressive than the 2660 and should be used if the level of adhesion of the 2660 is too low for a particular patient or clinical application.

These electrodes are for single use.

These electrodes will include the caution statement: U.S.A. Federal Law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use X **OR** **Over-the Counter Use** _____
(Per 21 CFR 801.109)